



Why Life Science Firms Shouldn't Fear the Cloud

*Debunking the Top Three Myths Regarding
Cloud-Based ERP for Life Sciences Firms*

By Peter Kowalke

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In some respects, you might say that life science firms, from medical device manufacturers to mid-sized pharmaceutical companies, are “pre-cloud” and waiting for their moment of digital disruption. The industry is like transport before Uber, or housing before AirBnB.

There's digital adoption, of course; no pharmaceutical company is using pen and paper for clinical trials or communicating with suppliers solely by phone. But the life science business is a conservative, slow-moving industry that is only slowly adopting the cloud model and embracing technology such as cloud-based ERP systems.

Only 15 percent of life science organizations use the cloud for more than sales and marketing efforts, according to a recent study conducted by global business intelligence firm, ORC International. For things like tracking, financials and the supply chain—the guts of the business—life science firms still are working from legacy on-premise solutions, spreadsheets, and a hodgepodge of systems stitched together.

“Such closed systems can create disadvantages,” notes a white paper by the digital consultancy, DXC Technology. “They tend to be expensive to maintain and don't scale easily. Data is typically spread among multiple, often siloed systems, making it difficult to manage and share. And while it seems to contradict conventional wisdom, closed systems can also hinder compliance with federal regulations.”

Don't Avoid Cloud Computing, Life Science

Much of this delay in adopting cloud-based solutions comes from regulatory fear. With exacting protocols for meeting FDA and other legal requirements, including iron-clad control and security, life science firms have taken a cautious approach while other industries have

plowed ahead and modernized their operations with all the advantages that come from the cloud. Everybody is getting disrupted except the life science industry and a few other holdouts such as the similarly regulated financial services industry.

This is slowly starting to change, however.

“Cloud computing and software-as-a-service (SaaS) IT models are revolutionizing most industry sectors around the world, and have had a profound impact on life sciences,” according to a recent brief by the global consultancy, Accenture. “This impact has been felt especially in the areas of sales and marketing.”

But now it gets harder for life science firms as they move beyond the marketing department and truly embrace the cloud for operations and the areas covered by regulation.

“Life sciences companies looking to extend the cloud's impact into areas such as R&D and the supply chain are encountering legitimate concerns about protecting intellectual property and demonstrating compliance with industry regulations regarding privacy and reporting,” the Accenture article noted.

Tackling the Myths Around Cloud Adoption

Fortunately, as Accenture acknowledged in its article, these concerns are largely unfounded. Cloud security is sophisticated and robust, and industry-specific solutions have been developed for life science firms that meet their strict reporting and compliance needs.

That is why the growth in cloud computing among North American healthcare and life science firms is growing by more than 20 percent per year, according to Markets and Markets research, with expectations that it will reach \$11.43 billion by 2020.



The only thing holding life science firms back from the cloud is fear and a few persistent myths. So let's look at three of those myths.

Myth #1: Cloud Security is Inadequate

The first myth that is slowing down life science firms from reaping the benefits of cloud computing is one that all industries faced when they first considered moving off their on-premise infrastructure: The cloud is not secure.

This is a particular concern for life science firms since there typically is a lot of intellectual property involved, and both privacy and control are heavily regulated in the industry. A pharmaceutical manufacturer or a healthcare services provider cannot afford a breach in security. It just can't.

So while other industries overcame their reservations about cloud security, industries such as life sciences and financial services are still jumpy about cloud security.

These concerns about security are not based on fact, however. As Constellation Research analyst Ray Wong

has noted, in most cases the cloud actually is more secure than on-premise corporate IT infrastructure; 60 percent of mission-critical data will be housed in the cloud by 2020 as a result.

That is because security is at the heart of the cloud business model, and so cloud providers both take security extremely seriously and actively maintain high levels of security and system maintenance—far beyond what most IT departments can muster on their own. The cloud model fails if businesses cannot trust it for security. So security is every bit as important for cloud providers as it is for regulated life science firms.

Encryption of data in transit and at rest, two-factor authentication, access controls, robust logging, real-time data backup and redundancy, containerization, immediate software patching and industry-specific security measures for compliance make the cloud more secure than on-premise systems, not less.

Myth #2: Cloud Solutions are Not Industry Specific

A second myth that plagues life science firms is that cloud options are too generic for the exacting and specific needs of a life science business. ERP and other cloud-based solutions are general and won't properly handle the dynamic demands and the specific requirements required for life science firms, the thinking goes, or they will require massive customization and implementation budgets to do so.

That might have been the case 10 years ago when other industries were first jumping aboard the cloud services bandwagon, but it no longer is the case. Life science firms now have a range of cloud options that have been tailored specifically for their needs and business models.

One example is Navigator Business Solutions' packaged ERP solutions for medical device and pharmaceutical manufacturers. Built on the robust, cloud-based SAP Business ByDesign platform, these solutions are built around specific life science business needs and come ready to handle areas such as Corrective and Preventative Action (CAPA), end-to-end traceability of lot/batch and serial number, embedded quality control and integration with outside quality control systems, industry-specific compliance systems, and systems to handle the journey toward FDA approval and management of complex multi-country supply chains.

Life science firms that are ready to make the jump to the cloud have industry-specific solutions already waiting for them.

Myth #3: The Cloud Doesn't Meet Compliance and Control Needs

The third myth that has slowed adoption of the cloud for life science firms is the fear that compliance and control measures are inadequate for the industry.

This is the big stopper for many companies, as noted above. Because life science firms must meet a host of regulatory hoops, including Good Manufacturing Practices (cGMP) validation and the FDA's CAPA requirement, there's the concern that cloud-based solutions are inadequate and not prepared for these strict and sometimes changing requirements.

This is a valid concern; the life science business is strict and filled with compliance needs. Taking a generic Oracle Cloud instance off the shelf and using it for a life science business absolutely will create problems.

Since the cloud has advanced to the point where there are specific solutions tailored to life science, however, this concern no longer applicable; processes and solutions have been developed for meeting a firm's specific regulatory needs, both for life science firms and other highly regulated industries.

These solutions are not static, either; they are automatically updated by cloud solution providers as regulations change, making the cloud arguably better able to meet the regulatory challenges than on-premise solutions that require manual update.

So while there still might be fear and mythology holding back life science firms from the cloud, there is no real reason for avoiding adoption. Life science just need to get over those fears and start enjoying the benefits other industries have realized from the cloud.



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